

### REMARKS

This is responsive to an Office Action mailed on December 15, 2004. In the Office Action, the Examiner rejected claims 1, 3, 4, 8-10, 13, 15, 34, 35, 38-40, 45 and 46, allowed claims 28, 29, 33 and 41-44, and objected to claims 14, 36 and 37. The present application currently includes claims 1, 3, 4, 8-10, 13-15, 28, 29 and 33-46.

In the Office Action, the Examiner rejected independent claims 1, 45 and 46 as being anticipated by the Cahalan et al. U.S. Patent No. 5,308,641 (hereinafter the Cahalan patent). In rejecting independent claims 1, 45 and 46, the Examiner alleged as follows:

Claims 1, 3, 4, 8, 9 15, and 45-46 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cahalan et al (US Patent 5,308,641) where the substrate as claimed is the polyalkylimine-coated tissue or other base material of Cahalan, and the growth factors are coated via glutaraldehyde (a difunctional aldehyde crosslinking agent) to it; see especially column 4, lines 20-43 and column 6, lines 8-28 and the abstract, column 4, lines 20-43 and column 6, lines 8-28. Cahalan discloses that one purpose of the surface treatment is to "promote the attachment and growth of a normal cell layer", see column 1, lines 33-43. For this reason, it stimulates the "association of viable cells with the substrate as claimed.

(Office Action mailed on December 15, 2004, page 3).

Applicant respectfully disagrees with the Examiner that the Cahalan patent anticipates independent claims 1, 45 and 46. Claims 1, 45 and 46 each define an invention as having crosslinking agents that comprise at least two aldehyde functional groups that form covalent bonds to link **the crosslinking agent directly with the polypeptide growth factor and the substrate.** (Emphasis added). The Cahalan patent does not disclose crosslinking agents that comprise at least two aldehyde functional groups that form covalent bonds to the link the crosslinking agent directly with the polypeptide growth factor and the substrate.

Rather, the Cahalan patent discloses a lightly crosslinked spacer consisting of a

polyalkylimine that is attached to a solid surface for the purpose of improving biocompatibility. (Col. 4, lines 14-19). The polyalkylimine is first applied to the solid surface and then is treated with the crosslinking agent. (Col. 6, lines 29-31). The polyalkylimine is reacted with a crosslinking agent where the reaction is completed in a few minutes. (Col. 5, lines 9-10) The crosslinking agent is used to lightly crosslink the polyalkylimine for the purpose of providing a polyalkylimine surface that allows a cellular adhesive molecule or other biomolecules to bond to the spacer. (Col. 4, line 62 – Col. 5, line 3; Col. 6, lines 8-10).

While the Cahalan patent does disclose a crosslinking agent, the Examiner fails to take into account the portion of the Cahalan patent, following the passage upon which the Examiner relied, that discloses the crosslinking is to be limited to the spacer molecules. The Cahalan patent discloses as follows:

The spacer of the present invention can therefore be made by applying a polyalkylimine to the solid surface and then **treating the applied polyalkylimine with the crosslinking agent**. Preferably, the cross linking agent used to **crosslink the polyalkylimine** is applied in a dilute solution and at a suitable pH to accomplish light crosslinking and to provide functionality for the polyalkylimine surface that will allow biomolecules to readily bond to the spacer.

(Col. 4, line 62-Col. 5, line 3)(Emphasis added). There is no disclosure in the Cahalan patent of a crosslinking agent that comprises at least two aldehyde functional groups that form covalent bonds to link the crosslinking agent directly with the growth factor and the substrate as claimed. Rather, the Cahalan patent discloses a lightly crosslinked spacer of polyalkylimine. Polyalkylimine, the only material that is disclosed as being crosslinked in the Cahalan patent, is neither the substrate nor the polypeptide growth factor. Therefore, the Cahalan patent does not anticipate claims 1, 45 or 46.

Further, an object of the invention disclosed in the Cahalan patent includes providing a surface for the attachment of biomolecules with a spacer of improved stability during handling and implementation of an implantable medical device. (Col. 2,

lines 58-62). Additionally, another object of the invention disclosed in the Cahalan patent is to provide a spacer which presents a stable platform for the attachment of the biomolecule and thereby prevents the attached biomolecule from being buried in the spacer layer. (Col. 2, line 63-66). The Cahalan patent only discloses attaching the biomolecule to the spacer.

Also, one questions the purpose of the spacer disclosed in the Cahalan patent if the Cahalan patent discloses a direct link between the polypeptide growth factor and the substrate with the crosslinking agent, as alleged by the Examiner. The direct linkage would bypass the spacer and, in fact, the spacer would become an impediment to the bonding that the Examiner alleges to be disclosed.

There is no mention of linking the cross linking agent directly with the polypeptide growth factor and the substrate in the Cahalan patent. Further, the entire disclosure of the Cahalan patent relates to a spacer that improves biocompatibility. The Cahalan patent does not teach how to circumvent the disclosed invention, a spacer for attaching biomolecules to an implanted medical device.

For the foregoing reasons, the Cahalan patent does not disclose each and every element of claims 1, 45 and 46. Specifically, the Cahalan patent does not disclose a crosslinking agent that comprises at least two aldehyde functional groups that form covalent bonds to link the crosslinking agent directly with the growth factor and the substrate, which is an element of claims 1, 45 and 46. As such, the Cahalan patent does not anticipate claims 1, 45 and 46. Reconsideration and allowance of claim 1, 45 and 46 are respectfully requested.

Since claim 1 is in allowable form, claims 3, 4, 8-10 and 13-15 which depend from independent claim 1 are also in allowable form. Reconsideration and allowance of claims 3, 4, 8-10 and 13-15 are respectfully requested.

Applicant respectfully requests that the obviousness rejections of dependent claims 10 and 13 be withdrawn. Cahalan does not teach the elements of claim 1, as discussed above, and Goldstein and Bayne do not supply the deficiency of Cahalan.

In response to the Examiner's double patenting rejection, Applicant submits that it may file a terminal disclaimer in the event that both the present application and copending application 09/014,087 issue into patents.

Applicant believes that the present application is in condition for allowance. Applicant respectfully requests that claims 1, 3, 4, 8-10, 13-15, 28, 29 and 33-46 be reconsidered and allowed.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Hallie A. Finucane at (612) 334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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